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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------|------------------|
| 10/682,045 | 10/08/2003 | Yih-Ming Hsiao | T-1264 | 8142 |
| 802 | 7590 | 09/22/2004 | EXAMINER | |
| DELLETT AND WALTERS P. O. BOX 2786 PORTLAND, OR 97208-2786 | | | HENLEY III, RAYMOND J | |
| | | | ART UNIT | PAPER NUMBER |

1614

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---|-------------------------------------|--|
| Office Action Summary | Application No. 10/682,045 | Applicant(s) HSIAO ET AL. | |
| | Examiner Raymond J Henley III | Art Unit 1614 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-16 is/are pending in the application.
- 4a) Of the above claim(s) 16 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4-10 and 15 is/are allowed.
- 6) ☒ Claim(s) 1,2 and 11-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

CLAIMS 1, 2 AND 4-16 ARE PRESENTED FOR EXAMINATION

Applicants' Amendment filed September 1, 2004 has been received and entered into the application. Accordingly, claims 1, 4-9, 11 and 12 have been amended, claim 3 has been canceled and claims 13-16 have been added. In light of the amendments, the claim objection and rejections under 35 U.S.C. §§ 112, second paragraph and 102, as set forth in the previous Office action are withdrawn.

Election/Restriction

Newly submitted claim 16 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claim 16 is directed to a method of treatment and is related to the composition/compound claims as product and process of use. These inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process as claimed could be practiced using a materially different product, e.g., the administration of another iron compound for the treatment of iron-deficiency anemia.

Claim 16 is also unrelated to the inventions of claim 4 which is directed to a process of preparing ferric citrate. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the methods have different modes of operation, functions and effects.

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Since applicants have received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 16 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejection - 35 USC § 103

Claims 1-3 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsu (U.S. Patent No. 5,753,706) in light of Applicants' acknowledgments at page 1, line 21 – page 2, line 3 of the present specification, each of record, for the reasons of record as set forth in the previous Office action as applied to claims 1-3, 11 and 12 and in further view of Webster's II dictionary (newly cited by the Examiner).

New claim 13 is properly included in the above rejection because it constructively represents a "product-by-process" type claim which defines a product and not a process.

Applicants' arguments have been carefully considered, but fail to persuade the Examiner of error in his determination of obviousness.

In particular, applicants have argued that because Hsu does not disclose ferric citrate having a fixed in molecular structure and definite mean number of water molecules, the rejection is improper.

The Examiner, however, cannot agree given the inherent characteristics of a molecule. That is, the ferric citrate of Hsu exists as molecules and, as defined by Webster's II, a molecule is "a stable configuration of atomic nuclei and electrons". Thus, being stable in nature, the molecules of ferric citrate taught by Hsu would not be variable or mutable and thus would exist in a fixed, definite state.

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That applicants have identified a ferric citrate having 3.5 parts of waters is not persuasive to the Examiner because (a) not all claims are limited to this specific hydrate of ferric citrate and (b) applicants have not established that a ferric citrate having 3.5 parts of water possesses any particular property that would not have been expected by the skilled artisan given the teachings of the references.

Allowable Subject Matter

Claims 4-10 and 15 are deemed allowable because the references of record fail to teach or suggest the presently claimed method for preparing ferric citrate.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

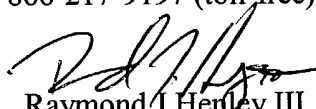
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Raymond J Herley III
Primary Examiner
Art Unit 1614

September 15, 2004